IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE MEDTRONIC, INC., IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABLITY LITIGATION	MDL No. 05-1726 (JMR/AJB) **MASTER CONSOLIDATED COMPLAINT FOR MEDICARE AS SECONDARY PAYER ACT CLAIMS**

NOW COMES Plaintiff, Billie Stubblefield, in her representative capacity as a "private attorney general" (hereafter "Plaintiff"), who brings this action for damages against Defendant pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute ("MSP"), 42 U.S.C. §1395y(b)(3)(A), to recover damages pursuant to the statute, of all Medicare expenditures made on behalf of Medicare beneficiaries in connection with Defendant's recalled defibrillator devices. Plaintiff makes the following allegations based upon her personal knowledge, and upon information and belief, as well as upon her attorneys' investigative efforts.1

I. NATURE OF THE CASE

1. On or about April 4, 2004, the United States Food and Drug Administration ("FDA") announced a Class I Recall of two models of Medtronic ICDs.

2. Ten months later, in February, 2005, Defendant notified physicians about the potential for a battery shorting action that may occur in the following Medtronic ICDs manufactured between April, 2001 and December, 2003: Model 7230 Medtronic Marquis VR, Model 7274 Medtronic Marquis DR, Model 7232 Medtronic Maximo VR, Model 7278

1 This Master Consolidated Complaint is filed in accordance with the January 20, 2006 Order of this Court. ¶17.A.2. This Master Complaint is submitted pursuant to the oral Order of Magistrate Judge Boylan at the February 16, 2006 Status Conference regarding the submission of a Master Complaint for claims alleging causes of action under the Medicare Secondary Payer Act. The lack of any references to Ms. Stubblefield's individual claims related to any individual injuries she sustained as a result of the defective product(s) in this litigation should not be deemed as a waiver of those claims, and those claims (i.e. set forth in the case Billie Stubblefield v. Medtronic, Inc., Court File No. 05-cv-2622-JRT-FLN) are expressly reserved under the Master Personal Injury Complaint filed with this Court on February 15, 2005 pursuant to the Pre-Trial Order dated January 20, 2006.

Medtronic Maximo DR, Model 7277 Medtronic InSync Marquis, Model 7289 Medtronic InSync II Marquis, Model 7279 Medtronic InSync III Marquis, and Model 7285 Medtronic InSync III Protect, all of which are collectively referred to herein as the "Recalled ICDs". Medtronic characterized the defect as "rapid battery depletion due to a specific internal battery short mechanism." Medtronic advised, "There is no provocative testing that predicts which of these devices will experience this issue. Once a short occurs, depletion can take place within a few hours to a few days, after which there is complete loss of device function."

3. Subsequently in March 2005 the FDA classified Medtronic's advisory actions as a recall.

4. The battery problem dated back to 2003 when Medtronic first detected a battery malfunction. The company modified the battery in an attempt to correct the problem in December 2003 although Medtronic failed to warn physicians, patients (including those already implanted with the device before these changes were made) and the public of these defects until the February 2005 notification.

5. Despite making the battery change, Medtronic continued to market, sell and distribute the previously manufactured devices - knowing they were defective and prone to failure - until the inventory was depleted. Patients continued to receive the defective devices for all of 2003, all of 2004 and at least until February 2005.

6. By reason of the wrongful conduct of Medtronic as alleged herein, a massive, national recall of approximately 87,000 heart devices has been underway in the United States. The overwhelming economic impact of Medtronic's conduct and the recall has fallen, wrongfully, on the shoulders of Medicare, which has been relegated to the position of primary payer for medical services arising from the recall.

7. Plaintiff brings this cause of action as a "private attorney general" pursuant

to the private cause of action provisions of the Medicare as Secondary Payer Statute [42 U.S.C. Section 1395y(b)(3)(A)] ("MSP") to recover "double damages" of all Medicare expenditures resulting from the Recalled ICDs.

8. Pursuant to the MSP, Medtronic is a "primary payer" directly responsible to Medicare for the reimbursement of health care costs resulting from the Recalled ICDs. As alleged herein Medtronic has, to date, avoided these reimbursement obligations to the Medicare program. Moreover, Medtronic has effectively caused the Medicare program to pay the full costs of Medtronic's obligations as warrantor of the Recalled ICDs – an excessive burden on the Medicare program in diametric opposition to the MSP statute.

9. Congress has expressly authorized private parties, like the Plaintiff, to bring a suit for damages against an entity, like Medtronic, and requires payment of all the health care costs incurred by Medicare on behalf of its beneficiaries in connection with the Recalled ICDs.

10. The MSP expressly authorizes a private action for the recovery of damages in an amount twice that of the health care costs paid by Medicare, which should have been paid by Medtronic. The Plaintiff seeks the recovery of such damages in this action.

II. PARTIES

11. At all relevant times, Plaintiff was a resident and citizen of the state of Texas and resides in Cross Plains, Texas. Plaintiff is a Medicare beneficiary. Medicare has paid and is being charged for the medical expenditures resulting from the Recalled ICDs. On May 20, 2003, Plaintiff was implanted with a Medtronic Model 7277 Medtronic InSync Marquis. Plaintiff had her Recalled Medtronic ICD explanted and replaced on March 10, 2005. Medicare paid her medical care costs. Plaintiff suffered personal injury as a result of the implantation into her and subsequent explantation of her faulty and defective Medtronic ICD which causes are expressly reserved under the Master Injury Complaint.

12. Defendant Medtronic, Inc. ("Medtronic") is a publicly traded corporation incorporated pursuant to and existing under the laws of Minnesota with its principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota.

13. Medtronic designs, develops, manufactures and markets medical products and describes itself as a "global leader in medical technology," posting $10.055 billion in revenue in 2004 as of April 29, 2005. It employs approximately 32,000 employees worldwide. More than 50% of all ICDs in the world are manufactured and sold by Medtronic.

14. Medtronic researches, develops, tests, manufactures, markets, promotes, advertises and sells implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices ("CRT-Ds"), including the capacitors and batteries required for their operation. Medtronic's Cardiac Rhythm Management (CRM) business "develops products that restore and regulate a patient's heart rhythm, as well as improve the heart's pumping function."

15. Medtronic's CRM business markets "implantable pacemakers, defibrillators, cardiac ablation catheters, monitoring and diagnostic devices and cardiac resynchronization devices, including the first implantable device for the treatment of heart failure." Through the CRM division, Medtronic developed, manufactured, tested, marketed and sold the Recalled Cardiac Devices, as well as the batteries required to power them.

III. JURISDICTION

16. This Court has Federal question jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under Federal statute 42 U.S.C. §1395y(b)(3)(A). This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332(a). Plaintiff alleges damages well in excess of $75,000.00.

17. This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and Defendant systematically and continually conducts

business throughout the state of Minnesota, including marketing, advertising and sales of the Recalled Cardiac Devices.

18. Venue in this jurisdiction is proper pursuant to 28 USC § 1391(a) as: (i) Medtronic maintains offices in Minnesota and its CRM Operations is headquartered in Minnesota; (ii) Medtronic sells and markets the Recalled Cardiac Devices within Minnesota and on a national basis; and (iii) Medtronic's CRM facilities operate in Minneapolis, Minnesota, its principal place of business for manufacturing, research and development, administration, sales and marketing, warehousing, packaging, shipping and safety reporting on/of medical devices (including the Recalled Cardiac Devices). Upon information and belief, the actions and conduct giving rise to the claims at issue took place and emanated from these facilities.

IV. THE MEDICARE AS SECONDARY PAYER STATUTE

19. Medicare is a health insurance program for the elderly and disabled, and is funded by the workers of America via contributions through payroll deductions. Under the Medicare program, the federal government pays for certain health care expenses of the aged (persons who are 65 years of age and older), the disabled, and persons suffering from the end stage renal disease. The Medicare program is the second-largest social insurance program in the United States, with 41 million beneficiaries and total expenditures of $280.8 billion in 2003.[2] The Trustees of Medicare have reported "the projected financial status of Medicare has taken a major turn for the worse."[3] It is estimated that by year 2019, the Medicare Hospital Insurance Trust Fund will likely be bankrupt.[4]

20. According to governmental studies, the majority of ICD recipients are 65

[2] See 2004 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.
[3] See Department of Justice Press Release No. 613 dated November 10, 2003.
[4] Social Security and Medicare Boards of Trustees, Status of the Social Security and Medicare Programs: A Summary of the 2004 Annual Reports, A Message from the Public Trustees. See also id., A message to the Public ("The financial outlook for the Medicare Hospital Insurance (HI) Trust Fund that pays hospital benefits has deteriorated significantly from last year.")

years of age or older and are thus eligible for coverage under the Medicare program. As an example, in the State of Connecticut for fiscal year 2004, Medicare paid for nearly 65% of all ICD therapy. In 2002 total Medicare reimbursements for ICD procedures were approximately $1.2 billion. As reported in the July 21, 2005, New England Journal of Medicine "The matter is particularly urgent because the number of people with ICDs is increasing rapidly. In 2003, the Center for Medicare and Medicaid Services paid for 52,500 ICD implantations; in 2004, it paid for 65,000. Hauser has estimated that worldwide more than 200,000 ICDs will be implanted or replaced this year. With expanded coverage, more than 500,000 Medicare beneficiaries may become eligible for an ICD." As recently reported by Sanford C. Bernstein & Company investment firm, the cost to Medicare and private insurers for defibrillators is expected to reach $10 billion, with Medicare covering about half that expense.

21. Medicare originated as a series of amendments to the Social Security Act. The MSP statute is found at section 1862 of the Social Security Act, and is codified as 42 U.S.C. §1395y. The MSP, in its present form, originated with the enactment of the Omnibus Budget Reconciliation Act ("OBRA") of 1980, Pub. L. No. 96-499, section 953, 94 Stat. 2599 (1980). The MSP was enacted in 1980 to reduce the Medicare program's rising costs. H.R. Rep. No. 1167, 96th Cong., 2d Sess. 352 (1980). The MSP statute functioned to reduce Medicare spending, as well as to insure the financial integrity of the Medicare program.

22. Since enacting the MSP statute, Congress has expanded its reach several times, making Medicare secondary to a great array of primary coverage sources. Congress has repeatedly clarified and augmented the Government's powers to recoup conditional Medicare payments from primary sources.

23. The Deficit Reduction Act ("DERFA") of 1984 conferred on the Government a direct right of action to recover its payments from any entity "which would be

responsible for payment," under a, "law, policy, plan or insurance."

24. In OBRA 1986, Congress added the private right of action for double damages codified at 42 U.S.C. § 1395y(b)(3)(A).[5] It also cross-referenced to § 1395(b)(2)(B)(ii), which enables the Government to collect double damages "in accordance with" the new private right of action. H. Res. 5300, 99th Cong., Sess., 100 Stat. (1986) at § 9319.

25. The MSP was again amended in 2003. On December 8, 2003, the President signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Modernization Act") [Pub.L. No. 108-173, § 301, 117 Stat. 2221]. Section 301 of the Modernization Act amends the MSP provisions, codified at 42 U.S.C. § 1395y (Supp. 2004). The title of Section 301(b) indicates that Congress regarded these amendments as "[c]larifying" the MSP statute. Section 301(d) further provides that the amendments therein are effective as if included in the MSP statute as originally enacted in 1980. In addition, both the Joint Conference Committee Report and the House Report clearly express Congress's intention that the Modernization Act clarify, rather than substantively change, the MSP statutes. *See* H.R. Conf. Rep. No. 108-391, at 571 (2003) (stating that the bill "*clarifies* that the Secretary may make a *conditional* Medicare payment if a...liability insurance policy or plan (including a self-insured plan)...cannot reasonably be expected to make prompt payment) (emphases added): H.R. Rep. No. 108-178(II), at 189 (2003) (explaining that the "Secretary's authority to recover payment from any and all responsible entities" under MSP "would be *clarified*") (emphasis added).

---

[5] The following excerpt from the Congressional Record exemplifies congressional sentiment as to whether Medicare was recouping as much from primary payers as it should: "Unfortunately, performance under the MSP program has not measured up. Failure to follow the MSP law is costing the taxpayers billions of dollars. ...Studies by the General Accounting Office and the inspector general of the Department of Health and Human Services have repeatedly identified the MSP program as gushing with leaks of Federal tax dollars." 135 Cong. Rec. S11848-01 (daily ed. Sept. 26, 1989) (statement of Sen. Durenberger) (discussing, in context of FY 1990 appropriations bill for health agencies, inadequacy of expenditures by Medicare intermediaries on MSP recoupment activity). See also GAO report on federal debt collection efforts (including lack of progress made in collecting MSP debts), Debt Collection Improvement Act of 1996: HHS's Centers For Medicare & Medicaid Services Faces Challenges To Fully Implement Certain Key Provisions, 2 (Feb. 2002) (referring to "Medicare Secondary Payer (MSP) debt, for which insurance *or other entities* are primarily financially responsible." (emphasis added)

26. United States Senator Charles E. Grassley, senior Senator from Iowa, Chairman of the Senate Finance Committee (which has exclusive jurisdiction over Medicare in the Senate) and author and sponsor of Section 301 of the Modernization Act clearly expresses the intent of Congress to apply the MSP to tortfeasors. To that end, Senator Grassley made the following statement in the Congressional Record:

> While the False Claims Act is one of our best weapons in the war on fraud and abuse, our policies in this new language of title III conference agreement adds more weapons to our arsenal. First, we make important technical clarifications to existing law that strengthen and improve what is known as the secondary payer statute...In addition, *when a Medicare beneficiary is injured by wrongful conduct of another entity, that entity's liability insurance or the entity itself, if it has no insurance, or it might be self-insured, is always required to pay first instead of having the taxpayers pay*. The provisions in title III do not change existing law in this area but, in fact, clarify the intent of Congress in protecting Medicare's resources.

(emphasis added) 149 Cong. Rec. S15574, S15584-S15585 (daily ed. Nov 22, 2003) (statement of Senator Grassley).

27. Section 301(b)(1) of the Modernization Act provides that "[a]n entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by failure to obtain insurance, or otherwise) in whole or in part."

28. With this language – stating that a business can create a self-insured plan through its failure to obtain liability insurance – Congress has plainly indicated that the term "self-insured plan" should be broadly interpreted, unrestricted by formalistic requirements. *See also* H.R. Rep. No. 108-178(II), at 189-90 (stating that the reason for adding the definitional sentence was to remedy the effects of "[r]ecent court decisions" that would allow "firms that self-insure for product liability" to be "able to avoid paying Medicare for past medical payments

related to the claim").[6]

29. Section 301(b)(2) of the Modernization Act provides that a primary plan shall reimburse Medicare for any payments Medicare has made if it is demonstrated that such primary plan has or had a responsibility to make such payments.

30. Section 301(b)(3) of the Modernization Act also provides that: "In order to recover payments made under this title for an item or service, the United States may bring an action against *any or all entities that are or were required or responsible* (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, as a large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. (emphasis added).

31. Moreover, section 301(b)(3) of the Modernization Act deleted the parenthetical phrase "including any physician or provider," thus further clarifying that there is no basis for narrowly interpreting the category of entities liable to reimburse Medicare.

32. The Modernization Act left intact and thus preserved the "private cause of action" for damages in accordance with the MSP statute. Though the United States may join or intervene in a lawsuit brought pursuant to this private right of action, whose assistance in protecting the integrity of the Medicare system is encouraged and would be welcomed, the

---

[6] *See also* Statement dated July 17, 2003 of William H. Jordan, Senior Counsel to the Assistant Attorney General, Civil Division, before House Committee on Ways and Means addressing section 301 of the MSP statute; "Finally, I would like to restate the Department's support for Section 301 of H.R. 1, the 'Medicare Prescription Drug and Modernization Act of 2003,' which would protect the integrity of the Medicare Trust Fund by clarifying that Medicare must be reimbursed whenever another insurer's responsibility to pay has been established. This section is consistent with the litigation positions taken by this Department of Health and Human Services in numerous court cases. Congress enacted the Medicare Secondary Payer ("MSP") statute in 1980 to protect the fiscal integrity of the Medicare program by making Medicare a secondary, rather than a primary payer of health benefits…The Medicare Trust Fund must be reimbursed, however once the primary insurer's obligation to pay is demonstrated... *the section makes clear that the Medicare program may seek reimbursement from a primary plan, from any or all of the entities responsible for or required to make payment under a primary plan*, and additionally from any entity that has received payment from the proceeds of a primary plan's payment. These provisions of section 301 will resolve contentious litigation and are designed to protect the fiscal integrity of the Medicare program." *Waste, Fraud, and Abuse: Hearing Before the House Comm. On Ways and Means,* 108th Cong. 88 (2003) (Statement of William H. Jordan, Senior Counsel to the Asst. Atty. Gen.) Available at 2003 WL 21667339 (emphasis added).

United States has no authority to intervene to the exclusion of the Plaintiff in this private right of action.

33. As currently codified, 42 U.S.C. §1395y(b)(2), the MSP provides, in relevant part, as follows:

> (2) **Medicare secondary payer.**
>
> (A) In general. Payment...may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that...payment has been made or can reasonably be expected to be made under a...**liability insurance policy or plan (including a self-insured plan)…. [T]he term "primary plan" means a...liability insurance policy or plan (including a self-insured plan)…. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise)** in whole or in part.
>
> (B) **Conditional payment.**
>
> (i) **Authority to make conditional payment.** The Secretary may make payment under this title with respect to an item or service **if a primary plan** described in subparagraph (A)(ii) **has not made or cannot reasonably be expected to make a payment** with respect to such item or service promptly….
>
> (ii) **Repayment required. A primary plan**, and an entity that receives payment from a primary plan, **shall reimburse...with respect to an item or service if it is demonstrated that such primary plan** has **or had a responsibility to make payment** with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.
>
> (iii) Action by United States. In order to recover payment made under this title...for an item or service, the United States **may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer...) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity**. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.
>
> (3) **Enforcement. (A) Private cause of action. There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement)** in accordance with paragraphs (1) and (2)(A). 42 U.S.C. § 1395 et seq. (emphasis added).

34. The statute provides that liability insurance is included as a source of

payment from a primary payer. The regulations adopted pursuant to MSP declare:

> Liability insurance means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance. 42 CFR Part 411.50.

35. For purposes of Medicare's right to recovery, the MSP does not distinguish between, but rather encompasses, both first party insurance coverage and third party (tortfeasor) insurance coverage. First party insurance coverages referenced in the statute include group health plans, large group health plans, workmen's compensation plans and no-fault insurance. Third party insurance coverages referenced in the statute include automobile insurance and liability insurance. 42 U.S.C. §1395y(b)(2)(A).

36. For purposes of Medicare's right to recovery, the MSP does not distinguish between, but encompasses, both ongoing litigation against primary plans and settled claims paid by primary plans. 42 U.S.C. §1395y(b)(2)(B)(ii).

A. Medtronic is a Primary Plan under the MSP which must fully reimburse Medicare for costs related to the Recalled ICDs

37. Pursuant to the MSP, Medtronic is a "primary payer" directly responsible to Medicare for the reimbursement of health care costs resulting from the Recalled ICDs. As alleged herein Medtronic has, to date, avoided these reimbursement obligations to the Medicare program. Moreover, Medtronic has effectively caused the Medicare program to pay the costs of Medtronic's obligations as warrantor of the Recalled ICDs – an excessive burden on the Medicare program in diametric opposition to the MSP statute.

38. Medtronic conducts its business pursuant to plans under which it has both

obtained product liability insurance and elected to increase substantially the degree to which it self-insures for product liability exposures. In fact Medtronic advised the Securities and Exchange Commission at page 24 of its Form 10-K filing on April 29, 2005 as follows:

> "At the beginning of fiscal year 2003, we elected to transition most of our insurance risks to a program of self-insurance.... This decision was made based on current conditions in the insurance marketplace that have led to increasingly higher levels of self-insurance retentions.... We will continue to monitor the insurance marketplace to evaluate the value to us of obtaining insurance coverage in the future. Based on historical loss trends, we believe that our self-insurance program accruals will be adequate to cover future losses...."

39. Moreover Medtronic's 2005 Annual Report (in a note to its Consolidated Financial Statements) provides as follows:

> "Self-Insurance. It is the Company's policy to self-insure the vast majority of its insurable risks including... product liability.... A provision for losses under the self-insured program is recorded and revised quarterly. As part of management's estimation process, the Company uses independent actuaries to help estimate the aggregate liability for disability and a significant portion of the product liability exposure.... Based on historical loss trends, the Company believes that its self-insurance program accruals are adequate to cover future losses...."

40. Medtronic in its 2005 Annual Report stated as follows: "In February 2005, we voluntarily advised physicians about a potential battery shorting mechanisim that may occur in a subset of our ICD and CRT-D models maunufactured between April 2001 and December 2003. ... Due to this voluntary field action, we estimate that approximately one-third of these units will be replaced and therefore we have established a reserve to cover the cost of units that

have been replaced and estimated future units to be replaced under this field action program."

41. Further Medtronic in its 2005 Annual Report also states under "Warranty Obligations": "The Company offers a warranty on various products. The Company estimates the costs that may be incurred under its warranties and records a liability in the amount of such costs at the time the product is sold. Factors that affect the Company's warranty liability include the number of units sold, historical and anticipated rates of warranty claims and cost per claim. *The Company periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. The amount of the reserve recorded is equal to the costs to repair or otherwise satisfy the claim.*" [emphasis provided]

42. When Congress passed the Modernization Act, it amended 42 U.S.C. §1395y(b)(2)(B)(iii) to permit actions against "any or all entities" that are or were required or responsible...to make payment...under a primary plan." This language is broader than the prior statute that permitted such actions against "any entity." Congress intended by the broader scope of this language to permit a broader scope of actions for recovery under the MSP.

43. The MSP statute provides that a private cause of action may be brought against any entity, such as Medtronic, that wrongfully shifts the burden of medical costs to Medicare. Medtronic cannot be permitted to "pass the buck" to Medicare in its responsibility for the full payment of the health care expenditures related to its defective devices.

44. Medtronic is a primary payer under MSP's first party insurer provisions. Medtronic has agreed to make payment of out of pocket expenses as part of its extended warranty programs. Medtronic has either knowledge or constructive knowledge that some of the recipients of the funds they are paying out had received Recalled Medtronic ICD-related medical treatment for which Medicare already paid. As a result, Medtronic is liable to reimburse the government pursuant to MSP.

45. An article in the July 21, 2005 edition of The New England Journal of Medicine reported as follows:

> "Since February 2005, there have been "an above-average number" of notifications to physicians about problems with ICDs.... In February, Medtronic (Minneapolis), the largest of these manufacturers, advised physicians about the potential for premature battery failure in some of its implantable defibrillators that could worsen over time.... Of 87,000 potentially affected units, about 13,000 had been replaced as of the end of May."

46. As reported in the August 11, 2005 edition of USA Today in an article titled "Patients with Defibrillators Face Tough Choice", Medtronic then expected even more of the 87,000 recalled units to be explanted and replaced by patients thereafter. As reported in the February 16, 2006 edition of the Bloomberg News "After Medtronic last year recalled their devices, 19,000 people had to have surgery for a replacement, said Medtronic spokesman Rob Clark." Medtronic, in its 2005 Annual Report, estimated "that approximately one-third of these units willl be replaced...."

47. Medtronic is a primary payer under MSP's third party tortfeasor insurer provisions. Medtronic carries liability insurance, or is self insured, from which a payment can reasonably be expected to be made.

48. Under the provisions of the MSP (as amended by the Modernization Act) Medtronic: (i) is a primary plan, (ii) that is responsible to pay for an item or service, and (iii) that has failed and/or refused to make appropriate payment to Medicare for the item or device.

49. Section 1395y(b)(2)(B)(ii) of the MSP, requires a primary plan to reimburse Medicare "if it is demonstrated" that the primary plan "has or had a responsibility" to make payment for an item or service. Applying this plain language, it is clear that Medtronic has or had such a responsibility and that it is improperly passing on this burden to Medicare.

50. Medtronic is obligated to pay for the Recalled ICDs has, in fact, already been established. Medtronic has admitted the defects inherent in the Recalled ICDs. Medtronic has established a program and/or agreement as part of its "supplemental replacement policy" to pay (under limited and specified conditions) for certain costs associated with the replacement of the Recalled ICDs. Medtronic has expressly agreed to provide a replacement device for certain of the Recalled ICDs (from its inventory of ICDs) and to provide un-reimbursed medical expenses (after Medicare payments) to patients for out-of-pocket expenses up to $2,500.

51. As reported in the February 16, 2006 edition of the Bloomberg News, "The company offered each patient who opted to switch defibrillators a free replacement and reimbursement of as much as $2,500 for expenses. Medical insurance providers and the government's Medicare health program were to cover the rest."

52. Defendant, despite its offer to replace the device, made no offer to reimburse the cost of the original defective device or to absorb the associated medical costs resulting from the replacement. Defendant offered merely to provide a replacement device and provide a small amount of money for unreimbursed medical expenses to patients, not to Medicare. Defendant's offer does not cover the medical costs of hospitalization and/or surgery stemming from device removal, replacement and aftercare, all of which is unconscionable. Defendants know this amount is insufficient to cover the costs of such medical treatment and will result in Medicare covering the difference in costs.

53. Further Defendant's offer to replace the Recalled Medtronic Devices (under limited conditions) with devices from its inventory is also unsatisfactory to some patients and doctors given the expected loss of confidence in Medtronic and consequently Medicare is also being wrongfully charged the cost of a non-Medtronic replacement device.

54. The Multicenter Automatic Defibrillator Implantation Trial II, a scientific

study of ICD therapy, ("MADIT-II"), addressed in part the costs of explantation and replacement of an ICD. MADIT-II reported in April 2004 that the "[c]ost of initial hospitalization for implantation ($23,000) plus device [ICD] ($25,000) was estimated at $48,000." MADIT-II conservatively assumed that ICD generator replacement would occur every 7 years (notwithstanding the manufacturers' claim that the ICD generators are replaced every 11 years) and that the average cost of ICD generator replacement is $21,742. MADIT-II also noted additional costs relative to monitoring and follow up after implantation of an ICD.[7]

55. Medtronic has pursued a means of wrongfully passing on to Medicare the full costs resulting from the Recalled ICDs. Notwithstanding Medtronic's knowledge that Medicare is wrongfully being billed as a primary payer for the substantial medical expenses associated with the replacement of the Recalled ICDs, Medtronic has only offered to pay up to $2,500 of patient's out of pocket expenses which are not covered by insurance.

56. Moreover, Medtronic's responsibility to make payment has been further demonstrated by the fact that there is an existing contractual relationship between Medtronic (as the primary payer) and the Medicare beneficiaries.

57. Medtronic's obligation to make payment for the replacement of the Recalled ICDs herein has already been established by the actions of Medtronic itself which has assumed responsibility for certain costs, however via concerted actions has improperly shifted the full costs to Medicare as primary payer in contravention of the MSP.

58. Medtronic warranted its Recalled ICDs and offered to pay device recipients $2,500 towards unreimbursed medical expenses (after Medicare). Medtronic cannot be allowed to limit its liability to "uninsured" medical expenses or make its liability secondary to payment

[7] These amounts are also exclusive of the medical costs resulting from complications (including the recognized risks of infection) and the costs of related component parts such as leads, etc. referenced in MADIT-II. As reported in the February 16, 2006 edition of the Bloomberg News, industry estimates forecast a 2 to 5 percent post-implantation infection rate after replacement of the Medtronic devices.

by Medicare. Medtronic must provide primary payment for the medical expenses associated with the replacement of the Recalled ICDs. Medicare is entitled to reimbursement from Medtronic for 100% of the related costs.

59. Medtronic should not be permitted to make Medicare the ultimate insurer and/or warrantor for the full costs stemming from its defective products. Medtronic's wrongful conduct directly affects the fiscal integrity of the overburdened Medicare program that the MSP was designed to protect.

V. FACTUAL ALLEGATIONS

60. This case involves, *inter alia*, Defendant's failure to warn doctors and patients of information within its knowledge or possession or both, indicating the Recalled ICDs were affected by a design and manufacturing defect making them unreasonably dangerous, unfit for their intended use, and that they posed health risks (including in some cases the risks of death or serious injury) to the ICD recipients.

61. Defendant designed, manufactured, marketed and sold the Recalled ICDs, touting the device's exceptional design and reliability in monitoring and regulating heart rhythm and reviving a person's heart during arrhythmia and/or arrest. Defendant marketed, promoted and represented that the Recalled ICDs were effective in providing life saving protection, increased patient safety, improved longevity and less frequent replacement. Defendant omitted material facts, intentionally withheld information regarding device malfunctions and mechanical design defects, and failed to timely and adequately warn the medical community, patients and the general public, thereby placing tens of thousands of people unnecessarily at risk without their informed consent.

62. Medtronic failed to timely warn doctors and patients of information within Medtronic's knowledge and possession that the Recalled ICDs were defectively designed and

manufactured, unreasonably dangerous, unfit for their intended use, and that they posed health risks to the recipients thereof, including in some cases the risks of death or serious injury. Medtronic placed thousands of Medicare beneficiaries unnecessarily at risk, forcing Medicare to assume substantial medical expenses. Medtronic has wrongfully caused and is causing the overburdened Medicare system to absorb the substantial health care expenses associated with its Recalled ICDs.

A. Defendant's Defective Devices

63. Cardiovascular disease is the leading cause of death in both women and men in the United States, claiming more lives every year than the five leading causes of death combined.

64. A normal heartbeat is the result of electrical impulses that originate in the sinoatrial (SA) node in the upper right chamber of the heart, known as the atrium. The impulse causes the atria to contract, causing blood to fill the ventricles. The impulse travels down to the ventricles causing them to contract, forcing blood out of the heart. This cycle repeats itself, resulting in a normal heartbeat.

65. If the normal electrical system malfunctions, an irregular heartbeat results, called an arrhythmia. Arrhythmias can prevent the heart from pumping enough blood throughout the body, leading to physical symptoms, tissue death, and cardiac arrest.

66. Certain persons with an arrhythmia require an ICD as a monitor and response mechanism. Similar to a pacemaker, the device monitors, regulates, and stabilizes in the event of either an increase or decrease in heart rhythm. When a person's heart stops normal pumping, the ICD automatically determines what type of treatment is needed, if any, and delivers it.

67. ICDs have been one of the most popular and fastest growing types of

medical devices.

68. It was expected that over 200,000 patients would receive an ICD in 2005.

69. According to Medtronic's June 29, 2005 Form 10-K, approximately two million of its cardiac devices have been implanted in patients worldwide.

70. Medtronic researches, develops, manufactures, promotes, advertises and markets products, including implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices ("CRT-Ds"), which focus on the treatment of cardiovascular and peripheral disease, cardiac arrhythmias, heart failure and slow heartbeats.

71. Essentially, all ICD's include a pulse generator, which is a small unit about the size of a pager, and one or two electrical wires extending out of the top, called leads.

72. The ICD is implanted in the upper chest near the neck and the leads run to the heart via blood vessels.

73. The ICD power source is a battery sealed within the device.

74. In the event of an increase or decrease in heart rhythm or sudden heart failure, electric currents are sent from the ICD through the insulated leads to the heart, which is shocked back into a steady rhythm. Patients who suffer from abnormally fast heart rhythms (tachycardia) rapid, ineffective contraction of the ventricles of the heart (ventricular fibrillation) or significant thickening of the heart muscle are also treated with ICDs to regulate heart rhythms.

75. The ICD is capable of correcting a heart beat that is too slow (bradycardia) or too fast (tachycardia) by delivering corrective treatment in the form of a series of electrical impulses. The patient may not feel the pulses, or it may feel like fluttering in the chest. It is painless.

76. The ICD is also capable of cardioversion. Cardioversion requires stronger electrical shocks than pacing, and it is designed to interrupt a harmful arrhythmia. Patients

report cardioversion is uncomfortable.

77. The ICD is also capable of defibrillation. Defibrillation involves application of a high-energy shock to the patient's heart and is appropriate treatment for very fast and irregular heartbeats called ventricular tachycardia (VT) or ventricular fibrillation (VF). Patients with either VT or VF usually faint or become unconscious and do not feel the powerful shock delivered during defibrillation. However, if they are not unconscious and/or are not in VT or VF when the ICD discharges a shock, they most certainly do feel the shock, and experience tremendous pain.

78. Without the aid of an ICD, the conditions set forth above and arrhythmias can lead to cardiac arrest or sudden death.

79. CRT-Ds are designed to provide mild electrical impulses to the two lower chambers of the heart to rectify and ameliorate heart failure symptoms and allow the heart to beat in a normal sequence.

80. During a heart failure episode, a patient's survival depends upon the success of the device at detecting the problem and shocking the heart back to a regular rhythm.

81. Without a prompt response, a patient's life faces great peril, and may require external resuscitation from medically trained personnel.

82. Every day, thousands of Americans rely on these devices to monitor their hearts and respond during a time of need.

83. If functioning properly, the ICD can save lives. If a device fails to engage during an arrhythmic episode, a patient in cardiac arrest has only minutes before permanent injuries or death occurs.

84. Through its CRM division, Medtronic developed, manufactured, tested, marketed and sold the Recalled Cardiac Devices described and discussed herein.

85. Through its CRM division, Medtronic also developed, manufactured, tested, marketed and sold the batteries used to power the Recalled Cardiac Devices described and discussed herein.

86. Medtronic Inc.'s facilities in Minnesota are the primary site of CRM operations.

87. Medtronic's CRM business – its largest business segment – includes all of its ICD and CRT-D devices, which accounted for nearly fifty percent of the company's worldwide sales. ICDs have been Medtronic's fastest growing product for the past three years: between 2002 and 2005, Medtronic's revenues from sales of the devices rose by nearly 63 percent from $2.944 billion to $4.615 billion.

88. In its public disclosures, Medtronic has represented to, *inter alia*, physicians and patients, that its ICDs and CRT-Ds are essential for saving lives.

89. Medtronic asserts that "[p]hysicians rely on our CRM products to correct these irregularities and restore the heart to its normal rhythm."

90. Medtronic asserts that is CRM products are "designed to treat a broad range of heart conditions."

B. The FDA and the Recalled ICDs

91. On or about April 4, 2004, the United States Food and Drug Administration ("FDA") announced a Class I Recall of two models of ICDs: Micro Jewell II (Model 7223Cx) and GEM DR (Model 7271) (collectively the "Class I Recalled ICDs").

92. On April 16, 2004, Medtronic issued a press release announcing the recall of the Class I Recalled ICDs.

93. Class I Recalls are instituted only when there exists a reasonable probability that use of the product will cause serious injury or death.

94. In the press release, Medtronic noted that it had become aware "of one serious injury and four deaths that may be related to the failure of the capacitor in a small subset of Micro Jewell II devices."

95. The Class I Recalled ICDs were found to have defective high voltage capacitors resulting in holdups in recharging the device's battery.

96. Medtronic asserted that such holdups could cause delays in the device's delivery of needed shock therapy or cause the device to fail to deliver that therapy when a cardiac arrhythmia occurs.

97. Delays in delivery or failure to deliver shock therapy during a cardiac arrhythmia can cause patient injury and/or death.

98. The recalled Micro Jewell II were manufactured between November 1996 and December 1997.

99. The recalled GEM DR were manufactured between May 1997 and August 1998.

100. On or about February 11, 2005, Medtronic initiated a worldwide advisory/recall regarding four additional models of ICDs manufactured between April 2001 and December 2003: Marquis VR (Model 7230); Marquis DR (Model 7274); Maximo VR (Model 7232); and Maximo DR (Model 7278) (collectively the "Recalled ICDs").

101. On or about February 11, 2005 Medtronic also initiated a worldwide advisory/recall regarding four models of CRT-Ds manufactured between April 2001 and December 2003: InSync Marquis (Model 7277); InSync II Marquis (Model 7289); InSync III Marquis (Model 7279); and Model 7285 (collectively the "Recalled CRT-Ds"). (The Class I Recalled ICD's, Recalled ICDs and the Recalled CRT-Ds are collectively referred to as the "Recalled Cardiac Devices.").

102. The FDA published Medtronic, Inc.'s notice regarding the Recalled ICDs and Recalled CRT-Ds and stated Medtronic was "advising physicians about a potential battery shorting mechanism" in the Marquis VR/DR and Maximo VR/DR ICDs and the InSync I/II/III Marquis and InSync III Protect CRT-D devices.

103. The Recalled ICDs and Recalled CRT-Ds contained a potential battery shorting mechanism.

104. When an ICD short-circuits, it causes the device to fail or stop working properly, placing the patient at significant risk of serious injury or loss of life when a cardiac disturbance occurs.

105. Without a medical examination during an actual failure, a patient would not know of an impending failure.

106. There is no provocative testing which will determine whether the devices referenced in this Complaint will fail.

C. The History of the Battery

107. A single battery powered the Recalled Cardiac Devices described and discussed herein.

108. The battery/ power supply was a Chi 4420L battery ("Chi").

109. The Chi is a member of the high-rate battery family containing the lithium/silver vanadium oxide chemistry.

110. The Chi was utilized in the following commercially approved ICDs: Model 7295, InSync II Protect, Marquis DR 7272, Marquis 7230, Maximo DR 7278, Maximo VR 7232, InSync Marquis 7277 and InSync II Marquis 7289.

111. The Chi manufactured and contained in the aforementioned devices (see paragraph 78) during the period covered by the Field Action was also known as Part #411310-06

("6").

112. The 06 was found to exhibit a shortening mechanism that resulted in sudden battery depletion during the accelerated bench testing.

113. Medtronic was aware that the 06 was at risk for sudden battery depletion resulting in internal shortening mechanism sometime during January 2003.

114. The 06 was redesigned in August 2003.

115. The redesigned Chi was known as Part #411310-07 ("07").

116. The 06 was redesigned to minimize the potential for internal shortening in the outermost turn of the battery coil.

117. After FDA approval of the redesign of the 06, Medtronic began manufacturing the 07.

118. After it began to manufacture the 07, Medtronic began manufacturing ICDs powered by the 07.

119. After Medtronic began to manufacture ICDs and CRT-Ds powered by the 07 it continued to sell ICDs and CRT-Ds powered by the 06.

120. Medtronic did not file a PMA request for the design of the 06.

121. The FDA never issued a PMA or PMA Supplement that reviewed and approved the design of the 06.

122. Medtronic filed a PMA Supplement request for the 07.

123. The predecessor power supply for the devices identified in paragraph 65 was the Chi 3625-7.

124. The Chi 3625-7 was replaced by the Chi 4420L battery after the Chi 3625-7 was found to be exhibiting a battery shortening mechanism.

125. During the Design Verification of the Chi 4420L there was at least one test

there an internal short was identified.

D. Medtronic Failed to Comply with FDA Requirements and Misrepresented the Safety of the Recalled Cardiac Devices

126. Medtronic did not advise the FDA of the risk of potential sudden battery depletion due to internal shortening mechanism in either January, February, March, April, May, June or July 2003.

127. Medtronic did not advise physicians of the potential for sudden battery depletion due to shortening mechanism until February 2005.

128. In or about August 2003, Medtronic requested approval from the FDA for a change in the batteries of the models covered by the February 2005 advisory/recall, without notifying the FDA of the reason for the change.

129. The FDA approved this change in October 2003 and ICDs containing the new battery began selling in December 2003.

130. Despite making the battery change, Medtronic continued to market, sell and distribute the previously manufactured devices – knowing they were defective and prone to failure – until the stock was depleted.

131. Certain Patients continued to receive the defective devices for all of 2003, all of 2004 and at least until February 2005.

132. In April 2004 Medtronic was aware that an implanted ICD and/or CRT-D powered by the 06 was found to exhibit the shortening mechanism that was identified during accelerated bench testing in January 2003.

133. During the period between April 2004 and December 31, 2004, Medtronic became ware of more than one ICD and/or CRT-D was found to exhibit signs of the battery shortening mechanism while the devices were implanted in patients.

134. Between January 2003 and February 9, 2005 Medtronic took no action to

prevent the implant of ICDs and CRT-Ds powered by the 06.

135. Between January 2003 and February 9, 2005 Medtronic did not advise physicians of the potential for sudden battery depletion of the 06 due to a shortening mechanism as identified in the accelerated bench testing performed in January 2003.

136. At all times relevant to this action, Medtronic misrepresented the safety of the Recalled Cardiac Devices, as well as their batteries.

137. At all times relevant, Medtronic negligently manufactured, marketed, advertised, promoted, and sold Recalled cardiac Devices that contained the 06 representing them as safe devices to be used for the prophylactic treatment of patients who have had, or may have, spontaneous and/or inducible life-threatening ventricular arrhythmias and patients who are at high risk for developing such arrhythmias.

138. At all times relevant to this action, Defendant knew, and/or had reason to know, that the Recalled Cardiac Devices were not safe for the patients for whom they were prescribed and implanted because the devices short circuit and malfunction and therefore fail to operate in a safe and continuous manner, causing serious medical problems and, in certain patients, catastrophic injuries and deaths.

139. As a result of their defective design and manufacture, the Recalled Cardiac Devices can cause serious physical trauma and/or death.

140. Defendant knew, and/or had reason to know, of the risk of injury and death and, by failure to disclose the information, prevented patients, and physicians from making informed decisions about the implantation of the ICDs and CRT-Ds at issue herein.

141. Furthermore, Defendant's concealment of the defect and failure to disclose the defect to physicians and Plaintiffs allowed the Recalled Cardiac Devices to be marketed and sold as safe for their prescribed use, when in fact they were not. This conduct amounts to a

deliberate act, which Defendant had reason to know was wanton, reckless and dangerous to patients and Plaintiffs.

142. Defendant never, directly, nor through any other means told Plaintiff or other ICD recipients about the known risks associated with the design and/or manufacturing defect, known to it, or which it reasonably should have known about, which existed in the ICD implanted into Plaintiff.

143. Defendant knew or should have known about the design and/or manufacturing defects associated with the ICD implanted in Plaintiff and all other ICD recipients, and had a duty to inform Plaintiff and all ICD recipients, about the risks associated with the design and/or manufacturing defects of the device.

VI. CLAIMS FOR RELIEF

COUNT ONE
(Liability as First Party Insurer Under MSP: Agreement to Pay Medical Costs)

144. Plaintiff realleges all previous paragraphs.

145. Medtronic is a first party insurer under the MSP as Courts have interpreted that statute from time to time.

146. Medtronic has acknowledged its obligation as first party insurer by agreeing to pay medical costs incurred in connection with the Recalled Cardiac Devices.

147. By Medtronic's acknowledgement of its obligation to pay such medical costs, it is a primary plan within the meaning of 42 U.S.C. §1395y(b)(2)(A).

148. Medtronic has an obligation to repay Medicare for all costs incurred with the Recalled Cardiac Devices because it has acknowledged a responsibility to make payment with regard to the Recalled Cardiac Devices, as required by 42 U.S.C. §1395y(b)(2)(B)(ii).

149. A private cause of action for such recovery is provided by 42 U.S.C.

§1395y(3)(A) because Medtronic has failed and refused to make the payments required by 42 U.S.C. §1395y(b)(2)(A).

150. Plaintiff is entitled to mandatory double damages pursuant to 42 U.S.C. §1395y(3)(A).

COUNT TWO
(Liability as First Party Insurer Under MSP: Provision of Express and Implied Warranties)

151. Plaintiff realleges all previous paragraphs.

152. Medtronic is a first party insurer under the MSP as Courts have interpreted that statute from time to time.

153. Medtronic has acknowledged its obligation as first party insurer by providing express and implied warranties directly to consumers of its products, and specifically the Recalled Cardiac Devices.

154. By Medtronic's provision of express or implied warranties, it is a primary plan within the meaning of 42 U.S.C. §1395y(b)(2)(A).

155. Medtronic has an obligation to repay Medicare for all costs incurred with the Recalled Cardiac Devices because it has acknowledged a responsibility under its warranties to make payment with regard to the Recalled Cardiac Devices, as is required by 42 U.S.C. §1395y(b)(2)(B)(ii).

156. A private cause of action for such recovery is provided by 42 U.S.C. §1395y(3)(A) because Medtronic has failed and refused to make the payments required by 42 U.S.C. §1395y(b)(2)(A).

157. Plaintiff is entitled to mandatory double damages pursuant to 42 U.S.C. §1395y(3)(A).

COUNT THREE
(Liability as Third Party Insurer Under MSP: Liability as Holder of a Liability Insurance Policy or Plan)

158. Plaintiff realleges all previous paragraphs.

159. Medtronic is a third party insurer under the MSP as Courts have interpreted that statute from time to time.

160. Medtronic maintains a liability insurance policy, or is self insured, from which payments for medical costs are made once liability has been established.

161. Medtronic has liability for damages incurred in connection with its Recalled Cardiac Devices. As a result of such liability, Medtronic's liability policy and/or its self insured plan is a primary plan within the meaning of 42 U.S.C. §1395y(b)(2)(A).

162. Medtronic has an obligation to repay Medicare for all costs incurred with the Recalled Cardiac Devices because it maintains a liability insurance policy, as set forth in 42 U.S.C. §1395y(b)(2)(B)(ii).

163. A private cause of action for such recovery is provided by 42 U.S.C. §1395y(3)(A) because Medtronic has failed and refused to make the payments required by 42 U.S.C. §1395y(b)(2)(A).

164. Plaintiff is entitled to mandatory double damages under pursuant to 42 U.S.C. §1395y(3)(A).

COUNT FOUR
(Negligence)

165. Plaintiff realleges all previous paragraphs.

166. Defendant had a duty to exercise the care of an expert in all aspects of the manufacture, testing, inspection, packaging, labeling, distribution, marketing, sale, withdrawal and recall of the ICD to insure the safety of its product and to insure that the consuming public, including the Plaintiff and their physicians and agents, obtained accurate information and instructions for the safe use or non-use of the implantable defibrillator.

167. Defendant failed to discharge this duty by distributing a defectively designed and/or manufactured device into the stream of commerce without warning or notice of the defects. Defendant's failure of duty exposed Plaintiff and other ICD recipients to life threatening physical trauma, including the risk of death. Defendant's failure of duty rendered Plaintiff's and other ICD recipients' physicians ignorant of information necessary to treat Plaintiff and other recipients of the Recalled Cardiac Devices.

168. In addition, Defendant's omissions and concealment of material facts were made with the understanding that patients and physicians would rely upon such statements when choosing Defendant's device. Furthermore, the economic damages and physical harm caused by Defendant's conduct would not have occurred had Defendant exercised the high degree of care imposed upon it and Plaintiff therefore plead the doctrine of *res ipsa loquitur*.

169. Medtronic was further negligent in manufacturing the devices described and discussed herein because:

a. the manufacturing processes for the defibrillators and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices;

b. the failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects, and

c. the Defendant failed to warn of the unreasonable risks created by these manufacturing defects.

170. Although the Food and Drug Administration's Pre-Marketing Approval process imposed requirements on the Defendant in connection with the manufacture and marketing of Medtronic defibrillators, it did not impose specific health or safety requirements on the device itself.

171. Defendant concealed the defects from the FDA, from physicians, and from

the patients who were to receive the devices.

172. Replacement of the defective devices requires costly surgery that can result in complications that may cause damage to the patient's heart and other injuries to the patient.

173. As a direct and proximate result of Medtronic's failure to provide timely and adequate warnings, and as a direct and proximate result of Medtronic's negligence, carelessness, and other wrongdoing and actions or omissions the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled ICDs have suffered damages including incurring health care costs that have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

COUNT FIVE
(Strict Liability: Design and Manufacturing Defect)

174. Plaintiff realleges all previous paragraphs.

175. Defendant manufactured, marketed, distributed and sold the listed devices in a condition which rendered them unreasonably dangerous due to their propensity to fail without warning.

176. The defibrillators manufactured by Medtronic and listed in this Complaint were unreasonably dangerous, because:

a. the manufacturing processes for the defibrillators and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices;

b. the failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects, and

c. the Defendant failed to warn of the unreasonable risks created by these manufacturing defects.

177. Medtronic's devices were defectively designed and manufactured because

the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the device.

178. The defects described and discussed herein existed when Defendants placed these devices into the stream of commerce.

179. The ICD was expected to and did reach Medicare beneficaries without substantial change or adjustment to its mechanical function upon implanting the device.

180. Defendant, the manufacturer of the ICD, knew or should have known of the design and/or manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design or formulation.

181. Defendant concealed the defects from the FDA, from physicians, and from the patients who were to receive the devices.

182. Furthermore, Defendant's ICD and its design and/or manufacturing defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

183. The ICD manufactured and supplied to Medicare beneficaries by Defendant was defectively designed and/or manufactured due to inadequate warnings or instruction because the manufacturer knew or should have known through testing or otherwise that the product created a high risk of bodily injury and serious harm. Defendant failed in providing adequate and timely warnings to consumers of the risk, both before sale and post-sale.

184. As a direct and proximate result of Medtronic's wrongful conduct, the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices have experienced health care costs related to the Recalled Cardiac Devices which have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

COUNT SIX
(Strict Liability: Failure to Warn)

185. Plaintiff realleges all previous paragraphs.

186. Defendant developed, manufactured, marketed, and distributed the ICD to the general public even after learning of design defect that threatened the intended use of the device.

187. The ICD models with design and/or manufacturing defects were expected to and did reach Plaintiff without substantial change or adjustment to its mechanical function upon implanting the device.

188. Defendant knew or should have known through testing, adverse event reporting, or otherwise, that the product created a high risk of bodily injury and serious harm.

189. Defendant failed in providing timely and adequate warnings or instruction regarding its devices with a known design and/or manufacturing defect.

190. As a direct and proximate result of Defendant's conduct, Plaintiff and other Medicare beneficaries who were implanted with the Recalled Cardiac Devices have incurred health care costs that have been paid by Medicare but are the responsibility of Medtronic, in an amount to be proven at trial.

191. Defendant's ICD is a product inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendant is therefore strictly liable to pay Medicare for the costs of the health care services resulting from the Recalled Cardiac Devices implanted in Plaintiff and all other Medicare beneficaries.

COUNT SEVEN
(Breach of Implied Warranty)

192. Plaintiff realleges all previous paragraphs.

193. At the time defendants designed, manufactured, produced, tested, studied,

inspected, labeled, marketed, advertised, sold, promoted, and distributed its ICD devices for use by Plaintiff, they knew of the use for which their devices were intended.

194. Defendant impliedly warranted its products to be of merchantable quality and safe and fit for their intended use.

195. Contrary to such implied warranty, Defendant's ICD device was not of merchantable quality, safe or fit for its intended use because the device was and is unreasonably dangerous and unfit for the ordinary purposes for which they were used, as alleged herein.

196. As a direct and proximate result of Medtronic's breaches of warranties, the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices have experienced health care costs related to the Recalled Cardiac Devices that have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

COUNT EIGHT
(Breach of Express Warranty)

197. Plaintiff realleges all previous paragraphs.

198. Defendant's concealment and failure to warn through promotional statements and product literature expressly warranted to the Plaintiff and other Medicare beneficaries who were implanted with the Recalled Cardiac Devices that such devices were safe, capable of reducing the risk or severity of heart failure, were highly reliable products in comparison to the conventional product lines.

199. In response to these promises and express statements, Plaintiff and other Medicare beneficaries relied on such affirmations and warranties through their physicians and surgeons.

200. The Recalled Cardiac Devices do not conform to those express representations in light of recently discovered disclosures and information previously withheld

by Defendant. Defendant's express warranty through its false statements failed to disclose and provide patient approval of the design and/or manufacturing defects inherent in the devices.

201. Defendant breached its warranty of the mechanical soundness of its ICD, by continuing sales and marketing campaigns highlighting the safety of its product, while it knew of the design and/or manufacturing defects and risk of product failure.

202. In allowing the implantation of the Recalled Cardiac Devices the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices relied on the skill, judgment, representations, and express warranties of Medtronic. These warranties and representations were false in that the Recalled Cardiac Devices were not safe and were unfit for the uses for which they were intended.

203. Through their sale of the Recalled Cardiac Devices, Medtronic was a merchant pursuant to Section 2-314 of the Uniform Commercial Code.

204. As a direct and proximate result of Medtronic's breaches of warranties, the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices have experienced health care costs related to the Recalled Cardiac Devices that have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

COUNT NINE
(Misrepresentation by Omission)

205. Plaintiff realleges all previous paragraphs.

206. Defendant misrepresented the mechanical soundness and reliability of its ICD devices to the general public through promotional and marketing campaigns. Defendant continued this misrepresentation for an extended period of time, without disclosing material information.

207. Defendant took advantage of the limited opportunity Plaintiff and other

Medicare beneficaries had to discover Defendant's strategic and intentional concealment of the defects in its ICDs.

208. Defendant concealed these design and/or manufacturing defects from the public by withholding information pertaining to the inherent design and/or manufacturing defects and high risks of failure relating to the Recalled Cardiac Devices, and presenting the devices as sound and reliable.

209. Defendant's intentional misrepresentations and omissions were made willfully, wantonly or recklessly to Plaintiff and other Medicare beneficiaries to induce the purchase of the Recalled Cardiac Devices over other pacemaker/defibrillators on the market.

210. Defendant knew or should have known of the high risk the Plaintiff and other Medicare beneficiaries would encounter by unwittingly agreeing to have implanted one of the Recalled Cardiac Devices.

211. As a direct and proximate result of Medtronic's wrongful conduct, the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices have experienced health care costs related to the Recalled Cardiac Devices that have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

COUNT TEN
(Violation of Minnesota False Statement in Advertisement Act)

212. Plaintiff realleges all previous paragraphs.

213. Defendant produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of its ICD, after learning of its inherent design defect, with the intent to sell its ICD devices.

214. Defendant concealed its deceptive practices in order to increase the sale of and profit from its ICD.

215. Defendant has violated Minn. Stat. § 325F.67 by intending to sell and create a customer demand for its ICD device using deceptive or untrue statements of fact about the device's mechanical soundness and reliability on Defendant's website and medical brochures distributed to patients and physicians.

216. The Minnesota statutes prohibiting false statements in advertising apply to all Plaintiff transactions with Defendant because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiff and other Medicare beneficiaries implanted with a defective device.

217. As a direct and proximate result of Medtronic's wrongful conduct, the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices have experienced health care costs related to the Recalled Cardiac Devices that have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

COUNT ELEVEN
(Violation of the Minnesota Prevention of Consumer Fraud Act)

218. Plaintiff realleges all previous paragraphs.

219. Defendant intentionally concealed its design and/or manufacturing defect and failed to disclose for the purposes of continuing the sale and distribution of its affected devices.

220. Defendant represented its ICDs as safe and effective and intended that patients and physicians rely on those representations when deciding if Defendant's device was optimal for meeting the patient's needs.

221. Through these misleading and deceptive statements and false promises, Defendant violated Minn. Stat. § 325F.69.

222. The Minnesota statutes prohibiting consumer fraud apply to Plaintiff and

other Medicare beneficiaries transactions with Defendant because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiff and other Medicare beneficiaries implanted with a device containing a design and/or manufacturing defect.

223. As a direct and proximate result of Medtronic's wrongful conduct, the Plaintiff and other Medicare beneficiaries who were implanted with the Recalled Cardiac Devices have experienced health care costs related to the Recalled Cardiac Devices which have been paid by Medicare, but are the responsibility of Medtronic, in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment against the Defendant as follows:

1. Damages in an amount double the amount paid by Medicare to reimburse health care providers for all health care services provided to Plaintiff and all other Medicare beneficiaries resulting from the Recalled Cardiac Devices, which expenditures Medtronic was required or responsible to make under The Medicare Secondary Payer Statute, one half of which shall be paid to reimburse the Medicare Trust Fund;

3. An award of attorneys' fees and costs of suit, as provided by law;

4. Such other legal and equitable relief as this Court deems just and proper.

PLAINTIFF HEREBY DEMANDS A JURY TRIAL.

DATED: February 21, 2006

ZIMMERMAN REED, PLLP

By: Robert R. Hopper

Charles S. Zimmerman, #120054
Ronald S. Goldser, #35932
Robert R. Hopper, #208760
ZIMMERMAN REED, P.L.L.P.
651 Nicollet Mall, Suite 501
Minneapolis, MN 55402

(612) 341-0400 – Telephone
(612) 341-0844 – Facsimile

JENNINGS & DRAKULICH L.L.P.
Nicholas J. Drakulich -
CA #98135 and NV#1407
2002 Jimmy Durante Blvd., Ste. 400
Del Mar, California 92014
(858) 755-5887 – Telephone
(858) 755-6456 – Facsimile

ATTORNEYS FOR THE PLAINTIFF